EUROPEAN COMMISSION

Brussels, 16.9.2010
C(2010)6440

COMMISSION DECISION

of 16.9.2010

amending the marketing authorisation for "Alimta - pemetrexed", a medicinal product for human use, granted by Decision C(2004)3580

(ONLY THE DUTCH TEXT IS AUTHENTIC)

COMMISSION DECISION

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amending the marketing authorisation for "Alimta - pemetrexed", a medicinal product for human use, granted by Decision C(2004)3580

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[2], and in particular Article 17(2) thereof,

Having regard to the notification submitted by Eli Lilly Nederland B.V., under Article 15(1) of Regulation (EC) No 1234/2008,

Whereas:

(1) The European Medicines Agency has informed the marketing authorisation holder and the Commission of its favourable opinion on the minor variation of type IB, notified between 11 January 2010 and 1 September 2010, and of the need to amend the decision granting the marketing authorisation.

(2) The marketing authorisation should be updated and Decision C(2004)3580 of 20 September 2004 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(3) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2004)3580 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)3580 is amended as follows:

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 334, 12.12.2008, p. 7.

1) The following notification for a minor variation is added to the marketing authorisation:

Application number	Scope (EU numbers affected)
EMEA/H/C/564/IB/27	B.II.f.1.b).1 (EU/1/04/290/001)

2) Annex I is replaced by the text set out in the Annex I to this Decision.

Article 2

This Decision is addressed to Eli Lilly Nederland B.V., Grootslag 1-5, 3991 RA Houten, Nederland.

Done at Brussels, on 16.9.2010.

For the Commission
Paola TESTORI COGGI
Director-General